

## PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

## PCT

NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL SEARCH REPORT AND  
THE WRITTEN OPINION OF THE INTERNATIONAL  
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

To:

Davies Collison Cave  
Level 15  
1 Nicholson Street  
MELBOURNE VIC 3000

Date of mailing 8 JUN 2004  
(day/month/year)

Applicant's or agent's file reference

12430560-TDO

FOR FURTHER ACTION See paragraphs 1 and 4 below

International application No.

PCT/AU2004/000389

International filing date

(day/month/year 29 March 2004

Applicant

PROSTATE DIAGNOSTICS PTY LTD et al

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes  
1211 Geneva 20, Switzerland, Facsimile No.: +41 22 740 14 35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

## 4. Reminders

Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the PCT Applicant's Guide, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/AU

AUSTRALIAN PATENT OFFICE  
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Authorized officer

JULIE GALE

Telephone No. (02) 6283 2272

**PATENT COOPERATION TREATY**  
**PCT**  
**INTERNATIONAL SEARCH REPORT**  
(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>12430560-TDO</b>	<b>FOR FURTHER ACTION</b> <div style="float: right; font-size: small;">see Form PCT/ISA/220 as well as, where applicable, item 5 below.</div>	
International application No. <b>PCT/AU2004/000389</b>	International filing date ( <i>day/month/year</i> ) <b>29 March 2004</b>	(Earliest) Priority Date ( <i>day/month/year</i> ) <b>28 March 2003</b>
Applicant <b>PROSTATE DIAGNOSTICS PTY LTD et al</b>		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 5 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the report**

- a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☒ Certain claims were found unsearchable (See Box No. II).

3. ☐ Unity of invention is lacking (See Box No. III).

4. With regard to the title,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

**"Diagnosis of advanced cancer"**

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

- a. the figure of the drawings to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

- b. ☒ none of the figures is to be published with the abstract.

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2004/000389

**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
  
2. ☒ Claims Nos.: 76-78  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:  
Claim 78 is directed to a pharmaceutical composition which comprises an agent capable of modulating the level of inhibin. The agent is defined merely by a desired result. There are no features which actually define the agent itself. Thus the scope of this claim is unclear and so broad that it is highly likely that known agents (either synthetic or natural compounds) would be encompassed within its scope. The addition of a carrier or diluent does not confer any novel aspect on this claim. The use of such an agent (claims 76 and 77) is also not clearly defined as the agent itself is not defined.
  
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

**Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
  
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2004/000389

## A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. <sup>7</sup>: G01N 33/574, 33/74, 33/68; A61K 38/00, 39/00; C12Q 01/68

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPAT; JAPIO; CAPlus; Medline (inhibin; neoplasm; neoplastic cell; (cancer/carcinoma/adenocarcinoma); (detect\*/diagnos\*/monitor\*/modulat\*/regulat\*)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 1995/032431 A1 (OXFORD BROOKES UNIVERSITY) 30 November 1995 Whole document.	51-54
X	WO 1987/005702 A1 (BIOTECHNOLOGY AUSTRALIA Pty. Ltd.) 24 September 1987 Whole document.	51-54
X	WO 2001/029079 A1 (PRINCE HENRY'S INSTITUTE OF MEDICAL RESEARCH) 26 April 2001 Whole document.	51-54
X	WO 1998/047526 A1 (MONASH UNIVERSITY) 29 October 1998 Whole document.	51-75



Further documents are listed in the continuation of Box C



See patent family annex

* Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

4 June 2004

Date of mailing of the international search report

8 JUN 2004

Name and mailing address of the ISA/AU

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## INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2004/000389

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	Sheth, N.A. et al., (1984) <i>Neoplasma</i> , vol. 31(3), pp 315-321. "Circulating levels of inhibin in cancer". Whole document.	1-54
X	Robertson, D.M. et al., (2001) <i>Molecular and Cellular Endocrinology</i> , vol. 180, pp 79-86. "Development of an inhibin $\alpha$ subunit ELISA with broad specificity". Whole document.	51-54
X	Betteridge A. and Craven, R.P. (1991) <i>Biology of Reproduction</i> , vol. 45, pp 748-754 "A two-site enzyme-linked immunosorbent assay for inhibin". Whole document.	51-54
X	Frias, A. E. et al., (1999) <i>Cancer</i> , vol. 85(2), pp 465-471. "Preoperative serum level of inhibin A is an independent prognostic factor for the survival of postmenopausal women with epithelial ovarian carcinoma". Whole document.	1-54
X	Mellor, S. L. et al., (1998) <i>Journal of Clinical Endocrinology and Metabolism</i> , vol. 83(3), pp 969-975. "Loss of the expression and localization of inhibin $\alpha$ -subunit in high grade prostate cancer". Whole document.	51-54
X	Petraglia F. et al., (1998) <i>Journal of Clinical Endocrinology and Metabolism</i> , vol. 83(3), pp 1029-1032. "Inhibin B is the major form of inhibin/activin family secreted by granulosa cell tumors". Whole document.	1-54
X	Robertson, D.M. et al., (2002) <i>Molecular and Cellular Endocrinology</i> , vol. 191, pp 97-103. "Inhibin/activins as diagnostic markers for ovarian cancer". Whole document.	1-54
A	Dowling CR and Risbridger GP (2000) <i>Endocrine-Related Cancer</i> , vol 7, pp 243-256. "The role of inhibins and activins in prostate cancer pathogenesis". Whole document.	1-75

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU2004/000389

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member			
WO 9532431		AU 25322/95	CA 2191061	EP	0763206
		FI 964657	US 5952182		
WO 8705702		AU 72036/87	EP 0260306	NZ	219609
		ZA 8701844			
WO 0129079		AU 10078/01	CA 2387576	EP	1226166
		NZ 518320	US 2003162229		
WO 9847526		AU 70151/98	EP 1011715		
Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.					
END OF ANNEX					